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10/20/03

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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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10/20/03

INVENTOR(S)						
Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)				
Ronald P.	Berger	Baltimore, MD				
Additional inventors are being named on the _____ separately numbered sheets attached hereto						
TITLE OF THE INVENTION (500 characters max)						
Catheter and Method For Ablation of Atrial Tissue						
Direct all correspondence to: CORRESPONDENCE ADDRESS						
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ENCLOSED APPLICATION PARTS (check all that apply)						
<input checked="" type="checkbox"/> Specification Number of Pages <u>7</u>						
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METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT						
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.						
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.						
<input checked="" type="checkbox"/> No.						
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[Page 1 of 2]

Respectfully submitted,

SIGNATURE [Signature]

TYPED or PRINTED NAME Heather Bakalyar, Ph.D.

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Date 10/20/03

REGISTRATION NO. 45,282

(if appropriate)  
Docket Number: 4301

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## INVENTION INFORMATION

**Title of Invention:**

Catheter and Method for Ablation of Atrial Tissue

School(s) and Department(s) in which invention was developed: School of Medicine, Dept. of Medicine

Additional inventors: ☐ Yes ☒ No If yes, please complete Additional Inventors section for each inventor.

**Lead Inventor Information:** ["The Lead Inventor is the primary contact person for LTD on all matters associated with this Report of Invention, including processing, patent prosecution and licensing. For reasons of administrative efficiency, it is the responsibility of the Lead Inventor to keep all other JHU inventors named on this Report of Invention informed of the status of such matters."]

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Are you a Howard Hughes Medical Institute employee or investigator?

☐ Yes ☒ No

Are you a Kennedy Krieger Institute employee or investigator?

☐ Yes ☒ No

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Field of Use 2E

## INVENTION DESCRIPTION

Describe the invention completely, using the outline given below. Please provide an **Electronic Copy** of the invention disclosure document, references, and abstracts, in Windows format, on CD-Rom or Floppy Disk.

**1. Abstract of the Invention** [In order to assist Licensing and Technology Development with the assessment of this technology, please provide a summary of the invention that should be written to be understood by a wide audience including non-technical individuals]

Atrial fibrillation is the most common sustained arrhythmia. It is associated with a high incidence of symptoms and with multiple medical sequelae including strokes. Often, atrial fibrillation is initiated (and possibly maintained) by electrical triggers located in the pulmonary veins, and can be cured or greatly suppressed by electrically isolating the pulmonary veins from the left atrium. A variety of catheter-based ablation strategies have been pursued to effect electrical isolation of the pulmonary veins (PVs), but none provides a simple convenient means for creating a ring of ablative lesions in the left atrium around the PV ostia. The present invention is designed to accomplish this ablation strategy.

**2. Problem Solved** [Describe the problem solved by this invention]

Current ablation strategies for atrial fibrillation do not provide a convenient simple means for placing a large ring of lesions around the pulmonary vein ostia. This invention solves the problem so that ablative lesions can be placed in a consistent fashion in the left atrium around the pulmonary vein ostia. (See attached.)

**3. Novelty** [Identify those elements of the invention that are new when compared to the current state of the art]

The disclosed ablation catheter has a lumen that exits the catheter just proximal to the deflectable part of the catheter. This allows a guidewire to be advanced through the lumen and anchored in a pulmonary vein. Once the catheter is deflected, the ablative tip electrode is positioned against the left atrial endocardium outside the PV ostium. Ablative lesions can then be placed as the catheter is rotated about the axis defined by the anchoring guidewire.


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This section is to be completed only by those JHU personnel subject to The Johns Hopkins University Intellectual Property Policy. Non-JHU Inventors, and HHMI or KKI Inventors at JHU are subject to a separate assignment and must complete Section C. JHU Inventors who believe they are not subject to The Johns Hopkins University Intellectual Property Policy for the invention described herein must complete Section C.

I/we, the Inventors, hereby certify that the information set forth in this Report of Invention is true and complete to the best of my/our knowledge.

I/we, the Inventors, hereby certify that I/we will promptly advise LTD of any commercial interest regarding the invention described herein.

I/we, the Inventor(s), subject to The Johns Hopkins University Intellectual Property Policy and not under an obligation to assign intellectual property rights to another party, hereby affirm that in consideration for The Johns Hopkins University's evaluation of commercial potential and a share of income which I/we may receive upon commercialization of my/our invention, on the date of my/our signature(s) as indicated below do hereby assign and transfer my/our entire right, title and interest in and to the invention described herein unto The Johns Hopkins University, its successors, legal representatives and assigns.

 JHU Inventor Signature	Ronald Berger Typed or Printed Name	7/10/03 Date
 JHU Inventor Signature	 Typed or Printed Name	 Date
 JHU Inventor Signature	 Typed or Printed Name	 Date
 JHU Inventor Signature	 Typed or Printed Name	 Date
 JHU Inventor Signature	 Typed or Printed Name	 Date

July 3, 2003

### Invention Disclosure

#### Catheter and Method for Ablation of Atrial Tissue

Inventor: Ronald D. Berger, MD, PhD  
Associate Professor of Medicine  
Johns Hopkins University

#### Background:

Atrial fibrillation is the most common sustained arrhythmia. It is associated with a high incidence of symptoms and with multiple medical sequelae including strokes. Recently, clinical investigators have found that in many cases, atrial fibrillation is initiated (and possibly maintained) by electrical triggers located in the pulmonary veins [1], and can be cured or greatly suppressed by electrically isolating the pulmonary veins from the left atrium [2].

A variety of catheter-based ablation strategies have been pursued to effect electrical isolation of the pulmonary veins (PVs). Initially, electrophysiologists used standard radiofrequency (RF) ablation catheters to place a sector or ring of lesions inside the proximal segment of these veins. This technique was found to be problematic because (1) success was limited due to the frequent incidence of arrhythmic triggers located at the PV ostia (proximal to the ablative lesions), and (2) the procedure carried an unacceptably high complication rate due to the subsequent development of pulmonary vein stenosis. Several catheters have been developed to apply circumferential lesions just inside the PVs using RF energy, ultrasound, or thermal energy [3-7]. These devices employ inflatable balloons or similar strategies to engage the PV and deliver energy in a radially symmetrical pattern. While these systems expedite PV isolation, they are complex to manufacture and do not solve the fundamental difficulties associated with ablating inside the PVs, listed above. A recently introduced ultrasound ablation balloon system is designed to apply a ring of lesions at the PV ostium instead of inside the vein [8], but this system is complex and will still place lesions distal to arrhythmic triggers located peri-ostially.

Electrophysiologists have recently migrated to ablation strategies in which ablative lesions are placed at the PV ostia, or even in the left atrium proper [9]. Again, the goal is to electrically isolate the PVs, but to do so with a wider ring of lesions and without placing lesions inside the PVs themselves. However, it is technically more challenging to place a set of contiguous lesions in a large ring outside the PV than to create a ring of lesions inside the vein. The ablation catheter tends to fall away from the wall of the left atrium as it is moved from point to point, making contiguity of the lesions difficult to achieve. Procedure times are often long and fluoroscopic radiation exposure can be substantial. Electroanatomical mapping techniques have been used to mitigate these problems, but manipulation of the

catheter to the many sites required for creation of large isolating rings of ablative lesions remains challenging, particularly due to the irregular three-dimensional shape and trabeculated endocardial surface of the left atrium.

#### Description of Invention:

The current invention is a novel catheter design that allows a wide ring of contiguous ablative lesions to be placed quickly and easily on the left atrial endocardial surface surrounding each PV. The catheter resembles a standard RF ablation catheter in that it contains a distal ablation electrode, at least one additional electrode placed proximal to the ablative electrode to allow for recording bipolar electrograms, and a deflection mechanism so that the distal portion of the catheter can be curved after it has entered the left atrial cavity.

The new catheter differs from existing deflectable ablation catheters, however, in that it has a lumen for passage of a guidewire, and the distal end of the lumen exits the side of the catheter just proximal to the deflectable portion (Figure 1). The relation of the lumen exit hole to the deflection mechanism is such that the distal portion of the catheter deflects away from the side where the lumen exit resides.

In another embodiment, the catheter has a rail along one side to allow a guidewire to be advanced along the outside of the catheter. Again, the rail ends just proximal to the deflectable portion of the catheter, and the distal portion deflects away from the side with the rail (Figure 2).

Use of the catheter is shown in Figure 3. A sheath is placed across the inter-atrial septum using standard technique. The ablation catheter is advanced through the sheath into the left atrium, and preferably manipulated into one of the pulmonary veins. A guidewire (preferably with a stiff body and soft distal segment) is advanced through the catheter so that it exits the side hole, and is further advanced deep into the vein. With the guidewire maintained in place, the catheter is withdrawn from the vein until it is back in the left atrial cavity. It is then deflected into the curved position, and advanced along the guidewire until the side of the deflected portion (including the ablation electrode) is in contact with the endocardial surface of the atrium, outside the PV ostium. Ablative energy is applied at this site, and the catheter is then rotated slightly about the axis of the guidewire to a new site. Ablative energy is applied, and the catheter is rotated again. This process is repeated until a full ring of lesions has been made. Alternatively, ablative energy can be continuously applied as the catheter is slowly and continuously rotated about the axis defined by the guidewire. In either case, the guidewire serves as an anchor to hold the catheter in radially symmetric positions relative to the vein ostium. The procedure may then be repeated for each PV.



This system provides advantages over current RF ablation catheters in that this catheter easily maintains endocardial contact over a nearly constant radius of distance outside the PV ostium. The exact curvature can be adjusted so that the catheter accommodates to the irregularities in the atrial endocardial surface. At all sites, the side of the ablation electrode is held in contact with the endocardial surface, producing larger and more consistent lesions than when the tip of the distal electrode contacts the tissue (as is often the case with current ablation catheters). Furthermore, a family of catheters can be manufactured with different radii of curvature to enable the operator to choose the appropriate radius of the ring of lesions, depending on the dimensions of the atrium in the individual patient. The catheter design is much simpler than that of inflatable balloon systems, so cost and device failures will be minimized.

The placement of a lumen in an ablation catheter for passage of an anchoring guidewire has been described [3,4,10]. However, in these previously described devices, a second, more distal anchoring guidewire is required and the catheter is secured simultaneously in two pulmonary veins, so that a line of ablative lesions can be placed from one PV ostium to another, rather than in a ring around a PV ostium. These previously described catheters lack a deflection mechanism to allow the distal portion of the catheter to be adjustably curved and rotated from site to site, as in the presently described invention.

The new catheter may include other design elements found in ablation catheters, such as a thermistor or thermocouple for temperature monitoring, and a position sensor to allow for electroanatomical tracking. An additional lumen may be added for fluid delivery to enable cooling during RF delivery. Furthermore, the ablative tip could be an ultrasonic or thermal device instead of an electrode if an ablative modality other than RF energy is preferred.

## References:

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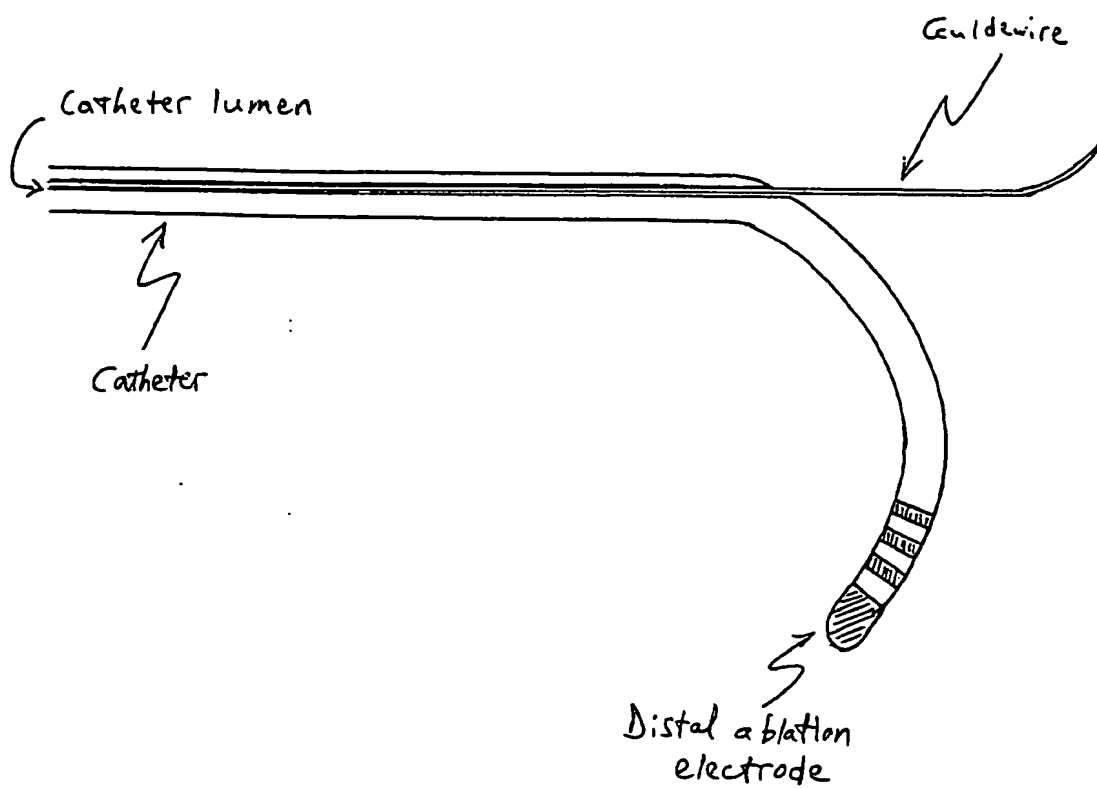


Figure 1

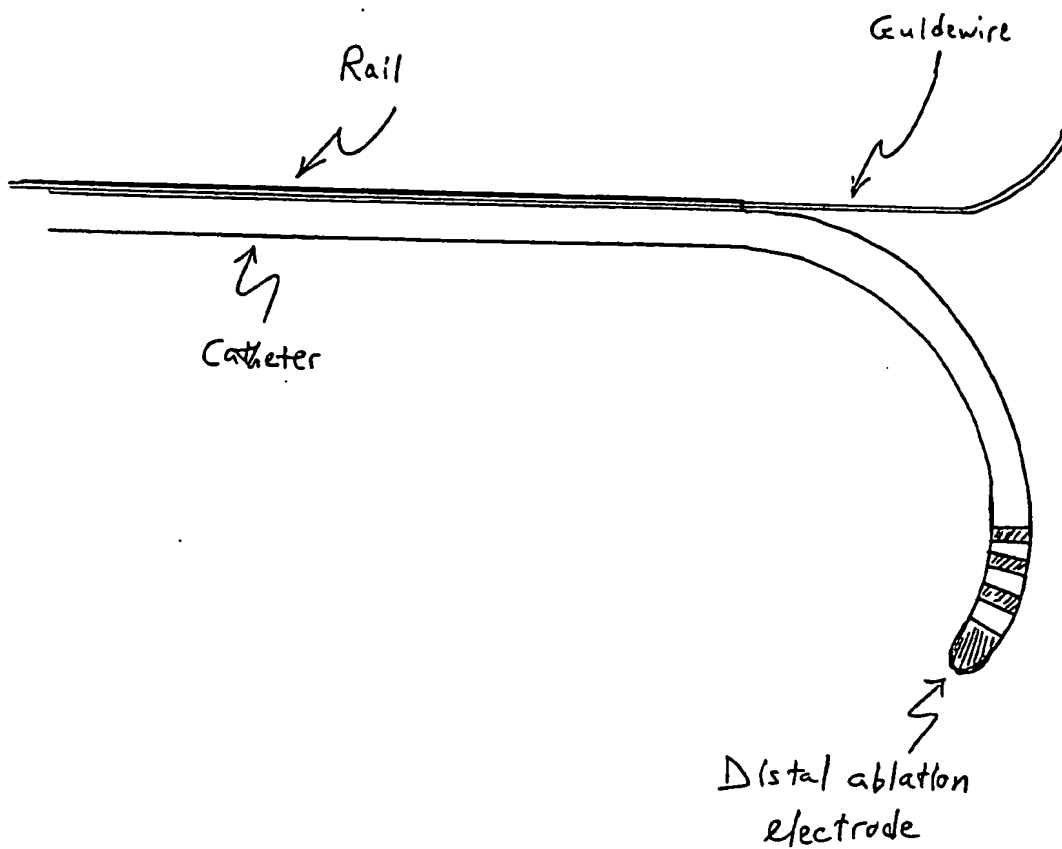


Figure 2

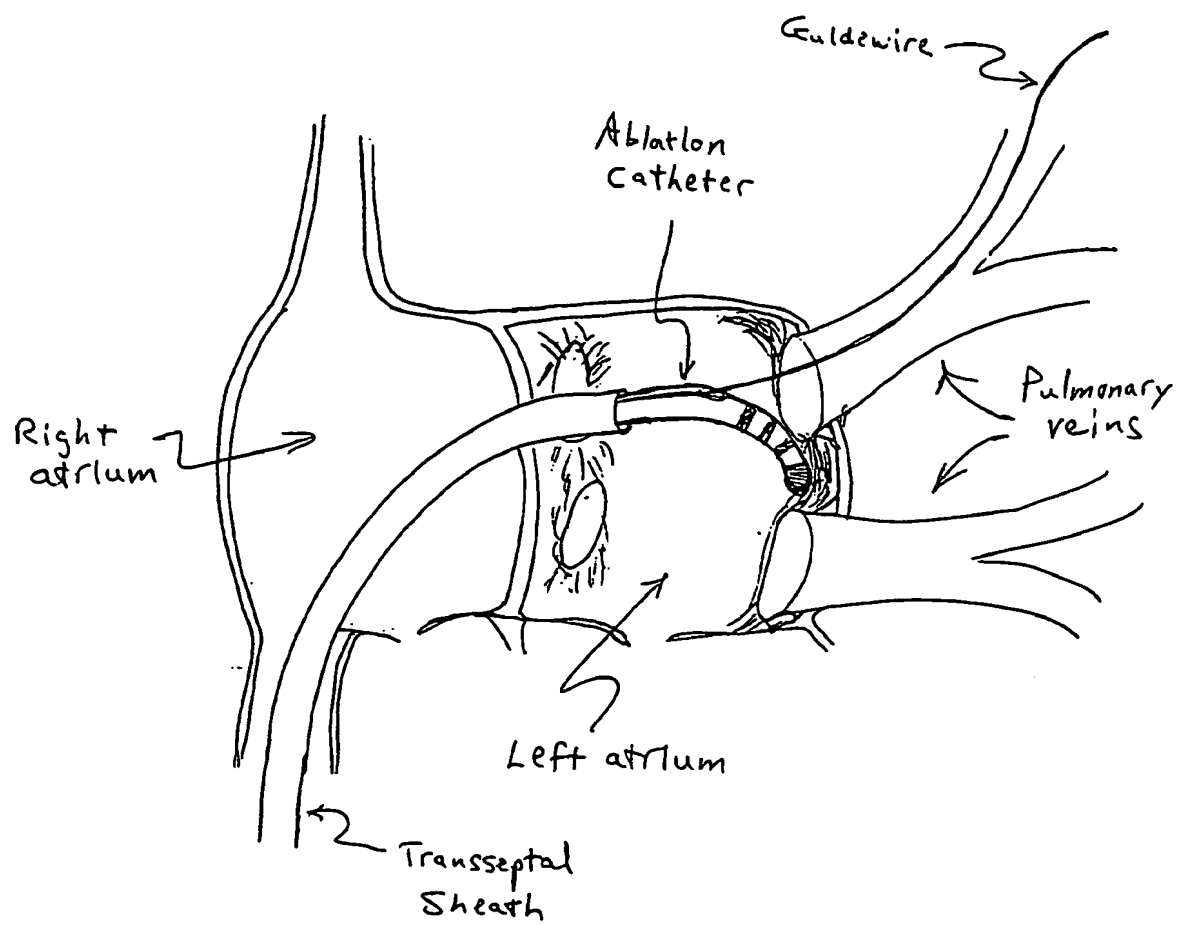


Figure 3

# Document made available under the Patent Cooperation Treaty (PCT)

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